

REMARKS

Claims 15 and 89-95 are pending in this patent application. The Office Action at page 1, however, makes no express reference to claims 91-95.

Claims 15, 89, and 90 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the data disclosed in relation to "Patient Profile 2" in Figure 1 of Hubbard, *et al.*, *Journal of Pharmaceutical Sciences* **1989**, 78:11, 944 ("the Hubbard reference"). Applicants respectfully request reconsideration because the cited disclosure in the Hubbard reference is not anticipatory. In this regard, Applicants provide herewith data demonstrating that the Ritalin SR product disclosed in the Hubbard reference does *not* exhibit the claimed ascending release rate profile over an extended period of time. In fact, as is discussed in the accompanying declaration of inventor Suneel Gupta, the rate at which the Ritalin SR product releases methylphenidate appears to actually *decrease* over an extended period of time. Dr. Gupta supervised an analysis, using the Wagner-Nelson deconvolution technique, of the plasma concentration data that the Hubbard reference reports in Figure 1 for Patient Profile 2 and in Figure 2 (Gupta Declaration, at ¶2). This type of data analysis, which is routinely performed by those skilled in the art (*id.*), approximates the release rate that the Ritalin SR product would have needed to achieve to produce the plasma concentrations that are reported in the Hubbard reference (*id.* at ¶3). As indicated by Dr. Gupta, this model clearly shows that the rate of release corresponding to Patient Profile 2 and Figure 2 does not ascend over an extended period of time but, rather, decreases (*id.* at ¶4).

Since the instant rejection of Applicants' claims was based on an alleged teaching of ascending release rates in the Hubbard reference – and since that teaching is not, in fact, present -- Applicants respectfully request that the rejection for alleged anticipation be withdrawn.

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Claim 88 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description. Although Applicants do not necessarily agree, they have canceled claim 88 to advance prosecution.

Claims 15, 89, and 90 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over certain claims of Application Serial No. 09/802,709. Since this rejection is provisional in nature, Applicants respectfully request that it be deferred until the instant claims have been allowed. Depending upon the prosecution status of Application Serial No. 09/802,709, the possibility exists that no issue of obviousness-type double patenting will, in fact, be presented.

Applicants also wish to bring to the Examiner's attention what appears to be a mistaken characterization of the instant patent application during the early stages of its prosecution. At page 9 of the Preliminary Amendment dated June 11, 1999, Applicants' attorney refers to an incorporation by reference of certain patent applications from which priority is claimed. The undersigned has not been able to find any such incorporation by reference.

Applicants also request that they be provided with an initialed copy of the Form 1449 that Applicants mailed on January 4, 2000. Although the information disclosure statement of which this form was a part is referenced in the Office Action mailed on May 20, 2000, an initialed copy of the form does not appear to have been transmitted.

Applicants also request an initialed copy of the Forms 1449 that they mailed to the PTO on April 23, 2003. The references cited in these forms also appear to have been considered, yet Applicants have not received a copy of the forms bearing the Examiner's initials.

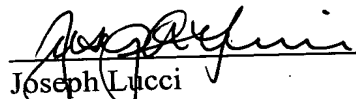
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As a formality, Applicants submit herewith a copy of Form 1449 listing the Patrick reference that is discussed in prior correspondence to and from the Examiner (*i.e.*, Patrick, *et al.*, *Biopharmaceutics & Drug Disposition* 1989, 10, 165). Applicants request that an initialed copy of the accompanying Form 1449 be returned along with those noted above.

Applicants invite the Examiner to contact their undersigned representative if any questions arise or further information regarding the instant patent application is needed. In view of the foregoing, however, Applicants submit that the pending claims are in condition for ready allowance, and therefore respectfully request an early indication of allowability.

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